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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

UNITED STATES OF AMERICA, Plaintiff, vs. DEL BUENO, a sole proprietorship, and JESUS RODRIGUEZ, an individual, Defendants.	NO. CV-12-3033-LRS CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, United States of America, by its undersigned attorneys, having filed a complaint for permanent injunctive relief against Del Bueno, a sole proprietorship, and Jesus Rodriguez, an individual (collectively "Defendants"), and Defendants having appeared and consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 et seq.

3. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food, within the meaning of 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

4. Defendants violate the Act, 21 U.S.C. § 331(k), by adulterating, or causing the adulteration of, articles of food within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce.

5. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the equitable authority of this Court, from directly or indirectly receiving, preparing, processing, packing, holding, and distributing articles of food, at or from their facility located at 695½ Wallace Way, Grandview, Washington, and any other locations at or from which Defendants, now or in the future, receive, prepare, process, pack, hold, or distribute any articles of food ("facility or facilities"), unless and until:

A. Defendants retain, at their expense, an independent laboratory (the "laboratory") having no personal or financial ties (other than the retention agreement) to Defendants or their families, which is qualified to collect product and environmental samples from within the facility or facilities and analyze those samples for the presence of Listeria monocytogenes ("L. mono") in a method that is acceptable to the United States Food and Drug Administration ("FDA"). Defendants shall notify FDA in writing immediately upon retaining such laboratory and shall provide FDA a copy of the service contract. Such service contract shall contain certain provisions, acceptable to FDA, for regular

environmental and finished product sample collection and analysis, including how and where to sample, the number and frequency of samples to be collected, and the methods of analysis, in accordance with the Listeria Monitoring Program discussed in paragraph 5(C) below;

B. Defendants retain, at their expense, an independent expert(s) (the "sanitation expert") having no personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, education, training, and experience, is qualified to inspect Defendants' facility or facilities and to determine whether the methods, facility or facilities, and controls are operated and administered in conformity with the Act and 21 C.F.R. Part 110. Defendants shall notify FDA in writing of the name(s) and qualifications of the sanitation expert(s) as soon as they retain such expert(s).

C. Defendants' sanitation expert, in consultation with the laboratory, after review of all FDA and Washington State Department of Agriculture ("WSDA") observations from 2008 to present, develops a written Listeria Monitoring Program, which shall include, at a minimum, the following:

(1) An effective written sanitation control program that establishes adequate methods, facility or facilities, and controls for receiving, preparing, processing, packing, holding, and distributing articles of food to minimize the risk of introduction of L. mono, other poisonous or deleterious substances, or filth into Defendants' food, and to ensure that foods are not adulterated, within the meaning of 21 U.S.C. § 342(a). Such methods, facility or facilities, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering the facility or facilities and all equipment therein suitable for use in receiving, preparing, processing, packing, holding, and distributing articles of food to prevent such articles from becoming adulterated, and instituting standard sanitation operating procedures ("SSOPs") to

ensure that the facility or facilities and equipment therein are continuously maintained in a sanitary condition;

(2) A written employee training program (in English and Spanish) that includes, at a minimum, instruction on sanitary food handling techniques and documentation that each employee has received such training. Defendants' expert shall ensure that each employee fully understands the substance of the employee training program;

(3) An effective program of environmental monitoring and testing of the facility or facilities to ensure that such poisonous or deleterious substances as Listeria species (L. spp.) are controlled, and such substances, including L. mono, are not present, within the facility or facilities. Environmental monitoring shall include, but not be limited to, collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the facility or facilities (where the raw ingredients, in-process, and finished articles of foods are received, prepared, processed, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analysis of collected samples, in a manner acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) calendar days of receipt by Defendants;

(4) A written plan for remedial action should L. spp., L. mono, or any other poisonous or deleterious substance be detected; and

(5) Assigning continuing responsibility for the operation of the Listeria Monitoring Program to a person or persons who, by reason of background, experience, or education, is competent to maintain the facility or facilities in a sanitary condition, coordinate with the laboratory, and implement any necessary remedial action(s), and providing such person with the authority to achieve the necessary corrections; and

(6) Defendants make English and Spanish versions of the Listeria Monitoring Program available and accessible to all their employees;

D. FDA has approved, in writing, the Listeria Monitoring Program discussed in paragraph 5(C) prior to implementation;

E. The sanitation expert conducts a comprehensive inspection of the facility or facilities and the methods and controls used to receive, prepare, process, pack, hold, and distribute foods to determine whether Defendants have effectively implemented all necessary corrections and are operating in compliance with this Decree, the Act, and 21 C.F.R. Part 110. The expert shall submit all findings to Defendants and FDA concurrently, within ten (10) business days of completion of the inspection;

F. Defendants report to FDA in writing the actions they have taken to bring their operations into compliance with the Act and all applicable regulations, including:

(1) Documentation that Defendants have cleaned and sanitized the facility or facilities and equipment therein and made improvements, thereby rendering the facility or facilities and equipment suitable for receiving, processing, preparing, packing, holding, and distributing articles of food, and documentation that Defendants have received laboratory confirmation from environmental swabbing that L. mono is no longer present in the facility or facilities; and

(2) Specific measures that they have taken to address each of the violations documented by FDA and WSDA since 2009;

G. Within thirty (30) calendar days upon entry of this Decree, Defendants shall destroy under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved prior to implementation, in writing, by FDA, all raw ingredients and all in-process and finished articles of food currently in their custody, control, or possession;

H. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and all applicable regulations, conducts inspections of the facility or facilities, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

I. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraph 5(A) through (G) of this Decree, the Act, and 21 C.F.R. Part 110; and

J. Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to paragraph 5(A) through (I), at the rates set forth in paragraph 11 below.

6. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree pursuant to paragraph 18 below, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce; or

C. results in the failure to implement and continuously maintain the requirements of this Decree.

7. Immediately upon resuming operations after completing the requirements of paragraph 5 and receiving notice from FDA pursuant to Paragraph 5(I), Defendants shall, in consultation with the laboratory and the sanitation expert, continuously implement the following steps to prevent further contamination from L. mono, other poisonous or deleterious substances, or filth in their food products and facility or facilities:

A. Effectively implement, on an ongoing basis, the Listeria Monitoring Program developed pursuant to paragraph 5(C) and approved by FDA pursuant to Paragraph 5(D), unless Defendants submit, and FDA approves in writing, an alternative L. mono control program, consisting of validated methods and controls that are shown to FDA's satisfaction to eliminate L. mono, other poisonous or deleterious substances, and filth in Defendants' food products and facility or facilities. In the event that Defendants, their sanitation expert, or laboratory, determines that the Listeria Monitoring Program needs to be revised, Defendants shall provide suggested changes to FDA in writing at least twenty (20) calendar days prior to their implementation, and shall not implement until they receive written approval from FDA.

B. Conduct environmental monitoring and testing to ensure that the SSOPs continue to eliminate the L. mono hazard and that the SSOPs are consistently being followed. Environmental monitoring shall include collecting swab samples from food-contact and non-food contact surfaces, equipment, and other environmental sites throughout the facility or facilities (where articles of food are received, prepared, processed, packed, and held, up to and including final packaging, as well as common areas), and analyzing such samples for the presence of L. spp. Environmental testing for L. spp shall be performed by the laboratory in accordance with timetables and methods that Defendants submit to FDA in writing for approval by FDA in writing before testing begins. Defendants shall ensure

that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) calendar days after receipt by Defendants.

Defendants' environmental testing must include, at a minimum, all of the following:

(1) if a food or non-food contact surface is found to be positive for L. spp. during routine testing, intensified sampling must be initiated as soon as possible, in conjunction with intensified sanitation measures;

(2) intensified sampling requires that three (3) samples per day must be collected and analyzed until a total of nine (9) consecutive samples (three (3) days of intensified sampling) have been taken and are negative for L. spp. from the site where the L. spp. was identified. After nine (9) consecutive samples are tested and found to be negative, and appropriate sanitation measures are taken, that site may be subject to routine sampling; and,

(3) all food products in the facility or facilities that test(s) positive for the general strain L. spp. must be placed on hold pending laboratory test results. The products can be released if laboratory test results are negative for L. mono; if the laboratory results are positive for L. mono, all food products manufactured from the time the laboratory sample(s) testing positive for L. mono were collected must be destroyed at Defendants' expense, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved prior to implementation, in writing, by FDA; and

C. Conduct finished product testing in the following manner:

(1) Defendants shall test for L. mono in all lots of each food product for at least five consecutive production days using a testing method approved in advance by FDA;

(2) After the completion of testing under paragraph 7(C)(1), Defendants shall test at least one lot of each food product per day for the next twenty (20) production days;

(3) After the completion of testing under paragraph 7(C)(2), Defendants shall test at least one lot of each food product per every five (5) production days for the next three (3) months; and

(4) After the completion of testing under paragraph 7(C)(3), Defendants shall test at least one lot of each food product per month thereafter.

D. If any laboratory test completed pursuant to paragraphs 7(C)(1)-(4) shows the presence of L. mono in any article of food, then Defendants must immediately cease production and notify FDA that production has ceased. Defendants shall also destroy, at Defendants' expense, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved prior to implementation, in writing, by FDA, all food products manufactured from the time the laboratory sample(s) testing positive for L. mono were collected. Defendants may resume production only when they have determined and corrected the cause of the microbial contamination and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Decree, the Act, and 21 C.F.R. Part 110. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under paragraph 7 anew. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) calendar days after receipt by Defendants.

8. If, after notifying FDA of the name of the laboratory retained to conduct sample collection and analysis pursuant to paragraph 5(A), Defendants terminate or alter their service contract with the laboratory in any way, Defendants shall notify FDA within five (5) business days. If Defendants terminate their service contract, Defendants shall provide a copy of the service contract with the new laboratory to FDA within five (5) business days of execution.

9. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the facility or facilities and, without prior

notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process, and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, preparing, processing, packing, holding, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

10. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least ten (10) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within ten (10) calendar days of providing a copy of this Decree to a prospective successor or assign.

11. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree. The costs of such activities shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per

representative for inspection or investigative work; $104.96 per hour or fraction thereof per representative for analytical or review work; $0.51 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

12. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, or other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing and order Defendants to take appropriate action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, preparing, processing, packing, holding, and distributing any articles of food;

B. Recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

C. Submit samples of articles of food to a qualified laboratory to determine whether they are contaminated with microorganisms or filth;

D. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

13. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses,

examinations, review, travel, and subsistence expenses to implement and monitor recalls and other corrective actions, at the rates specified in paragraph 11 of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

14. Upon receipt of an FDA directive described in paragraph 12, Defendants shall immediately and fully comply with the terms of the directive. Any cessation of operations as described in paragraph 12(A) shall be implemented immediately upon notice from FDA and shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations. After a cessation of operations, and while determining whether Defendants are in compliance with the Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

15. If any Defendant fails to comply with the provisions of the Act, its implementing regulations, and/or this Decree, then Defendants shall pay to the United States of America liquidated damages in the sum of two thousand dollars ($2,000.00) for each day that the Defendants fail to comply with this Decree; an additional sum of five hundred dollars ($500.00) in liquidated damages per day for each violation of the Act, its implementing regulations, and/or this Decree; and an additional sum equal to twice the retail value of each shipment of adulterated food. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

16. If any Defendant violates this Decree and is found in civil or criminal contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees (including overhead), travel expenses incurred by

attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

17. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered under this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

18. Within ten (10) calendar days after entry of this Decree, Defendants shall provide a copy of this Decree to each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) (in English and Spanish). Defendants shall provide to FDA within thirty (30) calendar days of the date of entry of this Decree, an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

19. Defendants shall prominently post a copy of this Decree (in English and Spanish) in an employee common area at the facility or facilities within ten (10) calendar days of the entry of this Decree and shall ensure that the Decree remains posted for a period of at least six (6) months.

20. Defendants shall, within ten (10) calendar days of the entry of this Decree, hold a general meeting or series of smaller meetings for employees of the facility or facilities, at which they shall describe the terms and obligations of this Decree (in English and Spanish, as necessary).

21. In the event that any Defendant becomes associated with any additional officers, agents, employees, representatives, successors, assigns, heirs, attorneys, or any additional persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such persons. Within ten (10) calendar days of each instance that any Defendant becomes associated with any such additional persons, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this paragraph, identifying the names, addresses, and positions of all person who received a copy of this Decree under this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving FDA's request for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

22. Defendants shall address all communications with FDA required under this Decree to the Director, Seattle District Office, United States Food and Drug Administration, 22201 23rd Drive SE, Bothell, Washington 98021-4421, and shall reference this civil action by case name and civil action number in such communications.

23. This Court shall retain jurisdiction of this action and the parties hereto for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this **3rd** day of **April**, ~~2011~~. **2012**

s/Lonny R. Suko

UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of this Decree:

For Defendants:

Jesus Rodriguez

JESUS RODRIGUEZ,
on behalf of Del Bueno

Jesus Rodriguez

JESUS RODRIGUEZ,
in his individual capacity

For Plaintiff:

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I hereby swear under the penalties of perjury that I am a certified interpreter of the English language into the Spanish language, and vice versa, and have been so recognized pursuant to Title 18, United States Code, Section 1827. I further swear that I have translated and read the Summons and Complaint filed in this matter, the Waiver of the Service of Summons, the Motion for Entry of Consent Decree, the Memorandum in support of motion for entry of consent decree, and the Consent Decree of Permanent Injunction to Jesus Rodriguez in Spanish.

Sworn this 12 day of MARCH, 2012

Certified Interpreter